K032790 Page 1 of 2

OCT - 2 2003

Exhibit A
510(k) Summary

Submitter: Siemens Medical Solutions USA, Inc.
Oncology Care Systems Group
4040 Nelson Avenue
Concord, CA 94520

Contact: Ken Nehmer
Manager of Regulatory Affairs

Phone: (925)602-8011
Fax: (925)602-8008
Email: ken.nehmer@siemens.com

Establishment Registration: 2910081

Proprietary Name: microMLC

Common Name: Accelerator, Linear, Medical

Classification: 892.5710
Class II device

Product Code: IXI

Substantial Equivalence Claimed To: Motorized Micro Multileaf Collimator (K000349)

Description:
The microMLC is a conformal radiation therapy and radiosurgery device that is mounted to a standard radiation therapy linear accelerator (Linac). The microMLC receives input from planning system software that determines the collimator aperture shapes at different gantry positions along the arc around the target area. Radiation is delivered at a constant rate.

The microMLC consists of three parts: (1) the user console, (2) the control cabinet and (3) the collimator mechanism.

The control cabinet with the user console serves as the control station for the operator and is located near the Linac operator console. If the system fails or the patient is endangered, the operator can push the emergency stop button that immediately cuts the power supply to all motors. The control cabinet contains the PC, an interface board and the power supply. The PC consists of a specified configuration of a CPU, motherboard, RAM, VGA board and HDD. It is used as the communication interface between the operator and the planning system software or the record and verify (R&V) system that contains the treatment positioning data. The PC also serves as the master for the control and verification system. The data received from the planning system software or the record and verify (R&V) system is processed and transferred to the micro-controllers on the control and verification boards.

The operator initiates position adjustment at the console or at the record and verify (R&V) system depending on the configuration. When an R&V system is involved the leaf positions are downloaded to the PC. The PC then starts all the micro-controllers simultaneously and retrieves the position of the leaves, comparing the values of the control system with those of the verification system.

The collimator mechanism is fitted to the accessory holder of the Linac gantry. It consists of 80 driving units that position the tungsten leaves. Eighty independent potentiometers for the verification system are included that serve as feedback for the verification system and checks the correct positioning of the leaves.

Intended use:
The microMLC is a conformal radiation therapy and radiosurgery device that delivers a shaped X-ray beam from a radiation therapy source. The microMLC is attached to a linear accelerator and consists of a series of pairs of tungsten leaves that collimate the radiation delivery to a target based on a treatment plan generated by planning software. The device is used to assist the clinician in the delivery of well-defined target volumes of radiation while sparing the surrounding tissues and organs.

Summary of technological considerations:
The Siemens Medical Solutions Oncology Care Systems, microMLC, is substantially equivalent to the cleared predicate device, Motorized Micro Multileaf Collimator K000349.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2003

Mr. Ken Nehmer
Manager, Regulatory Affairs
Siemens Medical Solutions USA, Inc.
Oncology Care Systems Group
4040 Nelson Avenue
CONCORD CA 94520

Re: K032790
Trade/Device Name: microMLC
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: II
Product Code: 90 IXI
Dated: September 5, 2003
Received: September 8, 2003

Dear Mr. Nehmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032790

Device Name: microMLC

Indications for Use:

The microMLC is a conformal radiation therapy and radiosurgery device that delivers a shaped X-ray beam from a radiation therapy source. The microMLC is attached to a linear accelerator and consists of a series of pairs of tungsten leaves that collimate the radiation delivery to a target based on a treatment plan generated by planning software. The device is used to assist the clinician in the delivery of well-defined target volumes of radiation while sparing the surrounding tissues and organs.

Prescription use:
The Siemens Medical Solutions Oncology Care Systems, microMLC, is intended to be used for medical procedures on patients to be prescribed and performed by a suitably trained and certified medical professional.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032790